

Notice of Allowability

Application No.

10/601,481

Examiner

Raymond J. Henley III

Applicant(s)

FENSOME ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and IDS filed February 7, 2006.
2. ☒ The allowed claim(s) is/are 1-7, 25 and 27-40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1/8/04 & 2/7/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SINGLE document.

RAYMOND HENLEY III
PRIMARY EXAMINER

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EXAMINER'S COMMENTS AND REASONS FOR ALLOWANCE

Comments

Applicants' amendment and Information Disclosure Statement filed February 7, 2006 have been received and entered into the application. Accordingly, claims 35, 38 and 39 have been amended. Also, as reflected by the attached, completed copy of form PTO/SB/08B, (1 sheet), the Examiner has considered the references cited by Applicants'.

Also attached is a completed copy of form PTO/SB/08B filed January 8, 2004, which indicates that the references listed thereon have been considered. The Examiner did not find in the present record a completed copy of this document.

In light of the above amendments, the objections to claims 35, 36, 38 and 39, as set forth in the previous Office action dated October 14, 2005, are withdrawn.

In Applicants' response at page 20, it is set forth that "[c]laims 36 and 40 depend on claim 35 and thereby include this amendment (sic). As amended, claims 35, 36 and 40 are in condition for allowance." Claim 40, however, depends from claim 39, which is an independent claim. Therefore, claim 40 does not depend from claim 35. Nevertheless, Applicants correctly state that claim 40 is in condition for allowance because claim 39 is in condition for allowance and claim 40 is in proper format.

Insofar as the above amendments have overcome the objections to claims 35, 36 and 38-40 and such claims were not subject to any further objection or rejection, these claims stand in condition for allowance. Also, as indicated in the previous Office action, claim 37 is also in condition for allowance.

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The reasons for allowing the remaining claims of record, i.e., claims 1-7, 25 and 27-34, are presented below.

Reasons for Allowance

The following is an Examiner's statement of reasons for allowance:

The presently claimed subject matter is directed to a method of inducing contraception comprising the administration of a progesterone agonist and one or more of a selective estrogen receptor modulator to a female of child-bearing age, (e.g., see present claim 1), as well as pharmaceutical kit useful in the practice of the above method which comprises said agonist and said one or more estrogen receptor modulator, (see present claim 28).

The closest art to the presently claimed subject matter is Zhang et al., (WO 00/66570; "WO '570), which, in the Examiner's opinion, (as set forth in the previous Office actions of record) discloses a genus of progesterone agonists of which Applicants' progesterone agonists are a subgenus. WO'570 further teaches that "PR [progesterone] agonists (natural and synthetic) are known to play an important role in the health of women. PR agonists are used in birth control formulations, typically in the presence of an ER [estrogen receptor] agonist", (page 1, line 29-31). The Examiner has concluded that it would have been obvious to select the presently claimed agonists from those disclosed in WO '570 and, in view of applied secondary references, concluded that it would have been obvious to employ estrogen receptor modulators of the type claimed in a method of contraception.

In Applicants' most recent amendment, they have traversed the above position of the Examiner by pointing out that the presently claimed sub-genus of progesterone agonists are not

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disclosed in WO '570 by way of a sufficiently small and particularly disclosed subgenus that would have rendered obvious the presently claimed progesterone agonists. By the manner illustrated by Applicants at pages 21-24 of their recent amendment, the Examiner is inclined to agree with Applicants.

Upon further consideration of the WO '570 reference, however, the Examiner has discovered that a particular species of Applicants' progesterone agonists is specifically disclosed. In particular, in present claim 25, for example, the compound "5-(4,4-Dimethyl-2-thioxo-1,4-dihydro-2H-3,1-benzoxazin-6-yl)-1-methyl-1H-pyrrole-2-carbonitrile" is disclosed in the WO '570 reference at Example 18 on page 54.

Therefore, in light of this disclosure, Applicants' arguments that "There is absolutely no direction in '570 to select the presently claimed substituents '...in a manner such that the presently claimed compounds would have clearly been obvious to one of ordinary skill in the art'." (Applicants' amendment at page 23, last paragraph), standing alone, does not possess sufficient import to outweigh the Examiner's conclusion of obviousness.

In addition to arguments, Applicants have presented data to show that the specifically claimed progesterone agonists possess an unexpected degree of potency, as compared to the other progesterone agonists disclosed by WO '570. It is proper to consider such evidence here, where the present rejection is made under 35 U.S.C. § 103, rather than § 102, ("Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing ... '(2) that there are new and unexpected results relative to the prior art.' *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004).", MPEP § 2144.05(III)). Further, while a species of Applicants is expressly

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disclosed, it is disclosed along with a significant variety of other progesterone agonists representative of the types compared in Applicants' amendment. That is, in WO '570, compounds having R⁵ as (i) a heterocyclic group other than a pyrrole ring or (ii) a substituted benzene ring are also specifically disclosed in WO '570, (see Examples 15-66 at pages 50-84) which is indicative of the fact that the artisan would have been faced with an option to use various compounds in order to practice the invention of WO '570.

The data presented in Applicants' amendment at pages 24-27, and the references containing a disclosure of such data, (see the IDS filed with Applicants' amendment), persuade the Examiner to find that the particularly claimed subgenus of compounds where R⁵ is a pyrrole ring having a cyano group attached thereto possess an unexpectedly superior degree of potency, as compared to the other compounds represented in WO '570 where R⁵ may also be either (i) a heterocyclic group other than a pyrrole ring or (ii) a substituted benzene ring. Nothing in WO '570 reference would lead one of ordinary skill in the art to expect that the claimed subgenus of compounds would possess the potency shown by Applicants' evidence.

The standard of patentability applied by the Examiner is the "preponderance of evidence" test. That is, the Examiner would have maintained the rejection if, in view of the art and evidence of record, it is more likely than not that the claims are unpatentable, (see, e.g., MPEP § 706(I)). Here, given the comparative data, the Examiner deems that the totality of the rebuttal evidence offered by Applicants of nonobviousness successfully outweighs the evidence of obviousness. In reaching the above conclusion, the Examiner has properly relied on the guidelines set forth under MPEP § 2144.08 for the examination of claims directed to species of

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chemical compositions based on a single prior art reference, especially under the heading "B. Determining Whether Rebuttal Evidence Is Sufficient To Overcome the Prima Facie Case of Obviousness".


Accordingly, for the above reasons, all claims currently pending are deemed patentable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
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5/11/06